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I, MICHELLE HENKEL, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ 3029 for a patent by ENDOGAD RESEARCH PTY LIMITED as filed on 23 September 1999.

I further certify that pursuant to the provisions of Section 38(1) of the Patents Act 1990 a complete specification was filed on 25 September 2000 and it is an associated application to Provisional Application No. PQ 3029 and has been allocated No. 37889/01.

WITNESS my hand this
Thirtieth day of September 2002

MICHELLE HENKEL
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AUSTRALIA

Patents Act 1990

ENDOGAD RESEARCH PTY LIMITED

PROVISIONAL SPECIFICATION

Invention Title:

Pre-shaped Intraluminal Graft

The invention is described in the following statement:

Field of the Invention

The present invention relates to an intraluminal device for use in the treatment of aneurysmal or stenotic disease.

Background Art

It is known to use intraluminal grafts and stents of various designs for the treatment of aneurysms such as aortic aneurysms, and occlusive diseases affecting the vasculature or other vessels comprising, inter alia, the hepato-biliary and genito-urinary tracts (which are all hereinafter "vessels"). It is known to form such an intraluminal device of a sleeve in which is disposed a plurality of wire stents (see Balko A. et al. (1986) *Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms*, 40 Journal of Surgical Research 305-309; Mirich D. et al. (1989) *Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study* 170(3) Radiology 1033-1037).

In the past, such devices have commonly been used in the treatment of aneurysms see for example United States Patent No 5782904 entitled "Intraluminal Graft". However, it has been recognised that it is within the ambit of some such devices that they also be used to treat stenotic lesions. Whatever the purpose for which an intraluminal device is being used, it has the capacity to be inserted percutaneously through a distal (or proximal) and connecting vessel to that in which the device is to be used, for example, through the femoral artery in a catheter, where the device is intended to be used in the treatment of a lesion within the aorta. Upon release of the device from the catheter it may expand to a desirable size, and may extend above and below the lesion thereby bridging the lesion. This method of inserting the device into the body of a patient is applicable where the invention is used in the treatment of aneurysmal disease or stenotic disease.

There are several potential problems associated with the known intraluminal devices. For instance, conventional grafts are not designed to follow the natural curvature of some vessels and may, therefore, kink if required to bridge a section of vessel that has a natural curvature.

Further to such natural curvature of a vessel, there may also be pathological curvature associated with aneurysmal disease. For example it is known that as an aneurysm situated in, for example, the aorto-iliac region expands, it can cause the artery to deviate in a direction towards the extending aneurysmal sac. This in turn may cause the vessel to shorten in

length across this section of artery which may sometimes result in displacement or kinking of any intraluminal device positioned in the artery.

The present invention is directed to an alternative form of intraluminal device which is designed to overcome the above problems.

Disclosure of the Invention

In a first aspect, the present invention consists in an intraluminal device comprising a tubular body having a length, a first end and at least one second end, wherein the tubular body has a pre-determined non-linear shape, the pre-determined shape corresponding with the shape of a non-linear portion of a vessel in which the device is to be disposed.

In one embodiment the tubular body is curved along its length between the first and the at least one second end.

In a further embodiment, the tubular body forms an S-shape along its length between the first and at least one second end

In another embodiment, the intraluminal device is a graft for bridging an aneurysm in an artery of a patient.

In a still further embodiment of the invention, when the intraluminal device is in situ within a vessel of a patient, the tubular body is configured such that it is curved along its length in an anterio-posterior plane.

In yet a further embodiment, when the intraluminal device is in situ within a vessel of a patient, the tubular body is configured such that it is curved along its length in a lateral plane.

In another embodiment, when the intraluminal device is in situ within the vessel of a patient, the tubular body is configured such that it is curved along its length in both an anterio-posterior and a lateral plane.

In a preferred embodiment, the length of the tubular graft body is made from a single piece of material that has been cut at such an angle so as to facilitate the curvature of the tubular graft body.

In a further embodiment, the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end.

In a still further embodiment of the invention, the shape of the vessel or vessel portion in which the device is to be disposed may be pre-determined and the device chosen or specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel

portion. The shape of the vessel or vessel portion may, in preferred embodiments, be determined by either ultrasound, plain abdominal films or by CT scanning. In this manner, the device is custom made from imaging of the vessel or vessel portion such that it fits securely within the vessel or vessel portion.

In a second aspect, the present invention consists in an intraluminal device comprising a tubular graft body having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end.

This has the advantage that when the device is disposed in a curved vessel, the first end of the tubular body continues to abut against the wall of the vessel in which the device is disposed even when the vessel deviates from its normal path due to pathological changes in that vessel or if the vessel has a natural curvature. Because the angled first end of the tubular body continues to abut against the surrounding wall of a vessel around substantially its entire periphery it forms a tight seal thereby reducing the likelihood of displacement of the device due to pathological deviation of a vessel from its normal path or due to the natural curvature of a vessel.

In a third aspect, the invention relates to the method for positioning an intraluminal device according to the first or second aspects of the invention, including the steps of introducing a catheter or other delivery device into a vein, artery or other vessel in the body of a patient when the device body is in a radially compressed state; causing the intraluminal device to be moved through the catheter or other delivery device until the intraluminal device extends into the vessel from a proximal end of the catheter or other delivery device; causing or allowing the intraluminal device to expand; and withdrawing the catheter or other delivery device along with any other apparatus used to introduce the intraluminal device into the vessel.

In one embodiment, the device is adapted such that it can be brought to a substantially straight configuration along its length and radially compressed to fit internal the catheter or other delivery device. The device is moved through the catheter or other delivery device until it extends from the proximal end of the catheter or other delivery device whereupon the device expands and takes on its pre-determined curved configuration.

In a further embodiment, the catheter may be configured such that it is slightly curved along its length. The catheter may be configured such that it is curved along its length in either an anterio-posterior plane or a lateral plane or in both planes.

The intraluminal device according to this invention may be used in the treatment of aneurysms or stenotic disease. In addition to treating aortic aneurysms the device is particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the subclavian artery. Further, in addition to the treatment of stenotic lesions in the peripheral vasculature, the invention may be used in the treatment of, inter alia, vessels comprising the coronary circulation. However the application of the invention for use in the treatment of stenotic disease is not to be understood as limited to the vascular system only, the device may be used to treat stenotic lesions in other vessels including, for example, those comprising the hepato-biliary and genito-urinary tracts.

In cases where the invention is to be used for the treatment of aneurysmal disease, the tubular device body is preferably formed of a thin biocompatible material such as Dacron™ or polytetrafluoroethylene (PTFE). The tube material is preferably crimped along its length to increase the flexibility of the device, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention for use in the treatment of aneurysmal disease, the device body may be formed from a material having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall, forming a seal between the wall of the device and the wall of the vessel such that the escape of the vessel contents into the aneurysmal sac is prevented.

In addition, in a further preferred embodiment, the device of all three aspects of the invention includes a stent or a series of spaced apart stents which forms a framework to which may be attached an endoluminal graft. The framework of the device body may be circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires. Each of such wires can have a generally closed sinusoidal or zig-zag shape. The wires are preferably formed of stainless steel or another metal or a plastic which is malleable and is biocompatible. If the device is adapted such that it is substantially straight along its length to facilitate packaging within a

catheter, the wires may be made from Nitinol™ or other such shape memory or heat sensitive material such that when the device is in situ within a vessel, the temperature in the vessel causes the material to take on a pre-determined configuration. The pre-determined configuration of the material in this embodiment causes the device to adopt a pre-determined curved configuration.

Each wire is preferably woven into the fabric of the device body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the device body during introduction of the device or throughout its life. If the device body is of a woven material the wires may be interwoven with the device body after its manufacture. If the device body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the device body. Alternatively the stent or stents may be continuous and may be on the radially inner or the radially outer side of the graft wall. In either case expansion of the graft or grafts will cause the graft to expand and press against the wall of a vessel into which the device has been placed. In one particular embodiment of the second aspect of the invention, the wires are adapted such that substantially the entire periphery of the angled one end of the tubular body is reinforced.

The tubular graft body may be of the self-expandable type wherein the wires are made from a shape memory or heat sensitive material. In this embodiment, the tubular graft body is ejected from the proximal end of the catheter and into the target vessel. Once in the vessel, the tubular graft body takes on its pre-determined shape. Alternatively, the tubular graft body may be compressed within the lumen of a catheter such that upon release of the tubular graft body from the proximal end of a catheter and into the target vessel, the tubular graft body springs into its pre-determined shape. In a further embodiment, the expansion of the tubular graft body within the target vessel may be aided by way of a balloon which, when inflated pushes the tubular graft body towards the wall of the target vessel.

In addition to or instead of being circumferentially reinforced, the tubular graft body may be longitudinally reinforced. In one embodiment, a longitudinally reinforcing wired may be connected to one or more circumferentially reinforcing wires. The advantage of longitudinal reinforcement is that the tubular graft body is less likely to compress along

its length during placement of the tubular graft body in the target vessel, resulting in a concertina effect.

In a still further embodiment the device of the invention is typically substantially of constant diameter along its length, that is, it is substantially cylindrical or may in some instances be frusto-conical in shape with a diameter that increases or decreases along the length of the device.

In another embodiment, the device of the invention is adapted to bridge an aneurysm that extends up to or slightly beyond an arterial bifurcation. In such a case the device is a graft which has a bifurcation at its downstream end, a so-called "trouser graft", and may be placed wholly within the primary artery. A supplemental graft may then be introduced through subsidiary arteries and overlapped with the lumen of the bifurcated part of the primary graft. In the case of an aneurysm in the aorta, for instance, that extended into each of the common iliac arteries the primary graft would be placed in the aorta. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the common iliac arteries.

Brief Description of the Drawings

One preferred embodiment of the invention is now described with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by a device according to the present invention.

Figure 2 is a simplified view of a device according to the prior art.

Figure 3 is a simplified view of a device according to the present invention.

Figure 4 is a detailed longitudinal view of an aortic aneurysm that is bridged by a device according to the prior art.

Figure 5 is a detailed longitudinal view of an aortic aneurysm that is bridged by the device of the present invention.

Figure 6 is a side elevational view of an aortic aneurysm that is bridged by a device according to the prior art.

Figure 7 is a side elevational view of an aortic aneurysm that is bridged by the device of the present invention.

Figures 8a and 8b are representations of a delivery mechanism of one embodiment of the invention.

Best Mode of Carrying out the Invention

An endovascular graft according to the present invention is generally shown as 10 in the drawings. The endovascular graft 10 is adapted for insertion transfemorally into a patient to achieve bridging and occlusion of an aneurysm 11 present in an aorta 12. It is to be understood that the present invention has a wider applicability and could be utilised in vessels other than the aorta. As is shown in Figure 1 the aorta 12 bifurcates to form the common iliac arteries 13 which subsequently divide into the external 14 and internal 15 iliac arteries, the external iliac artery 14 eventually becoming the femoral artery 16. The aortic aneurysm is located between the renal arteries 17 and 18 and the junctions of the bifurcation of the aorta 12 into the common iliac arteries 13. The graft 10 is inserted inside a catheter 9 and introduced into one of the femoral arteries 16 of a patient. Once the catheter 9 is located appropriately with its proximal end in the aorta 12 the graft 10 is ejected from the catheter and expanded so that each end 19 and 21 is in intimate contact around its full periphery with the aorta 12. The graft 10 then bridges the aneurysm 11 and isolates any thrombosis or gelatinous material associated with the aneurysm outside the graft 10 to reduce the risk of embolisation.

The endovascular graft 10 comprises a tube 22 of woven Dacron™. The tube is reinforced along its length with a plurality of separate spaced apart wires that are interwoven in the Dacron™. Between the two ends 19 and 21 the body of the tube 22 curves in a manner that enables the graft 10 to follow the natural or pathological contours of the aorta.

Figures 2 and 3 indicate the difference between the graft of the present invention 10 and conventionally used grafts 23. The conventionally used grafts 23 are substantially straight in design and do not account for either natural curvature of an artery or pathological curvature due to the ballooning and pulling effect of an aneurysm 11. Accordingly, when an aneurysm 11 starts to expand and the aorta 12 is pulled and forced to curve away from its normal path, the grafts of the prior art 23 can become dislodged at end 24 (see Figure 4) or kink at a point 25 along their length, (as depicted in Figure 6).

The benefit of the present invention can be seen in that the graft 10 is pre-curved to align with the aorta 12 which is pulled from its natural path due to the ballooning of an aneurysm 11. Furthermore, end 19 of the graft 10

is angled such that it still abuts against the walls of the aorta 12 when the aorta 12 is curved out by the pull of the aneurysm. In conventional grafts 23, as the aorta 12 is curved, the end 24 of the graft may not fit against the walls of the aorta 12 and the graft can have a tendency to dislodge as a result. This can be seen in Figures 4 and 5 where the section of aorta 12 proximal the renal arteries 17 and 18 deviates towards the expanding aneurysm such that an angle is formed. The angle may in some cases be up to 90^0 and thus the straight shaped conventional grafts 23 sometimes do not fit securely within the aorta 12, becoming dislodged.

Whilst the graft 10 is adapted to take on a pre-determined configuration such that it aligns with a non-linear vessel, the graft 10 may be inserted into a target vessel in a substantially straight configuration. Figure 8a and 8b depict one means of introducing a graft 10 into a vessel by way of a catheter 9. The graft 10 is forced into a substantially straight configuration within the catheter 9. When positioned correctly within a target vessel, the graft 10 may be ejected from the catheter 9 by way of, for example, a push rod 30 whereupon the graft 10 takes on its pre-determined curved configuration (shown in Figure 8b).

In use, the shape of the vessel in to which the device is to be disposed may be imaged and the device chosen or specifically manufactured such that the shape of the graft 10 corresponds with the shape of the vessel. Imaging may be by way of ultrasound, plain abdominal films or by CT scanning. In this manner, the graft 10 is custom made such that it fits securely within the vessel.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty third day of September 1999

ENDOGAD RESEARCH PTY LIMITED
Patent Attorneys for the Applicant:

F B RICE & CO

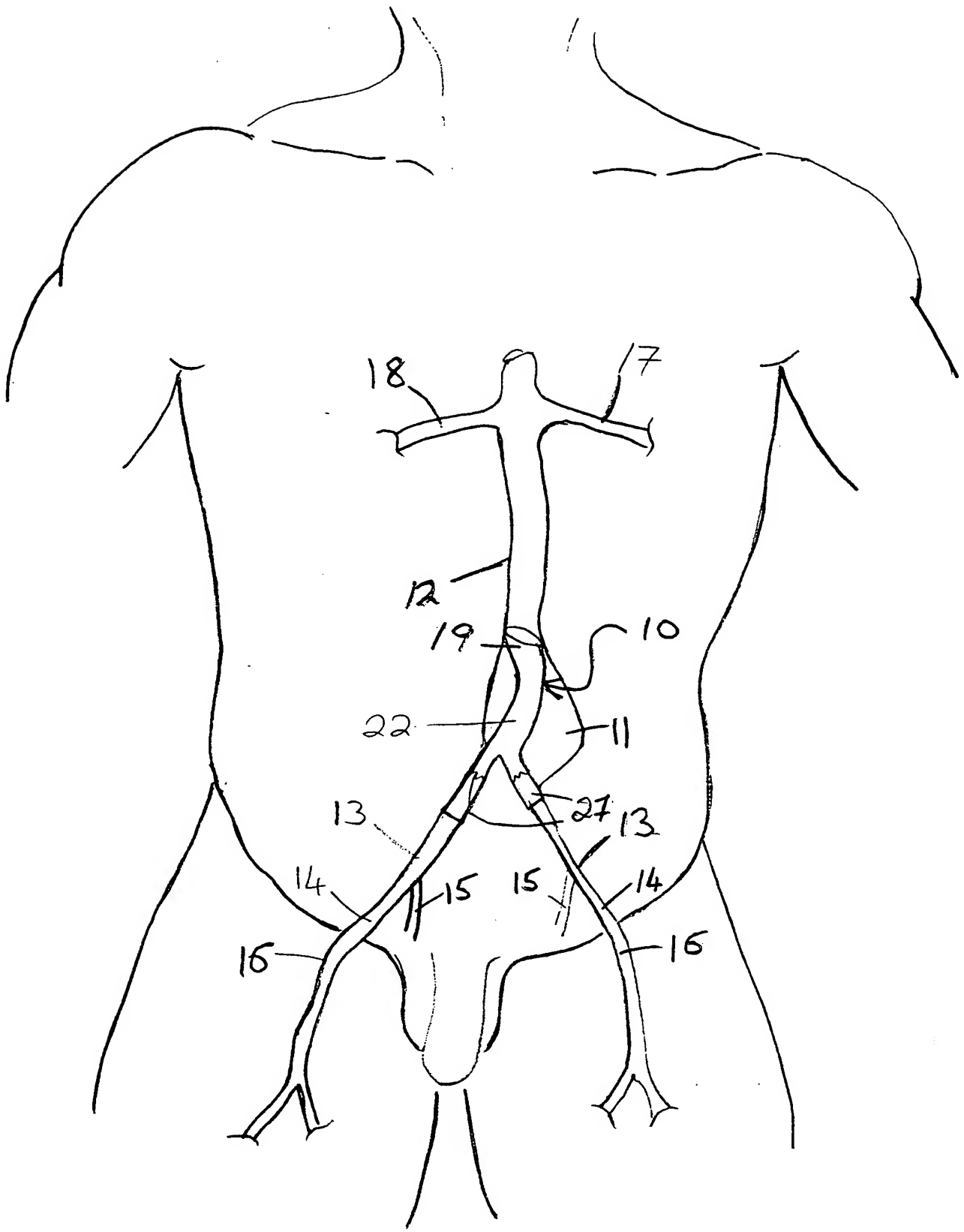
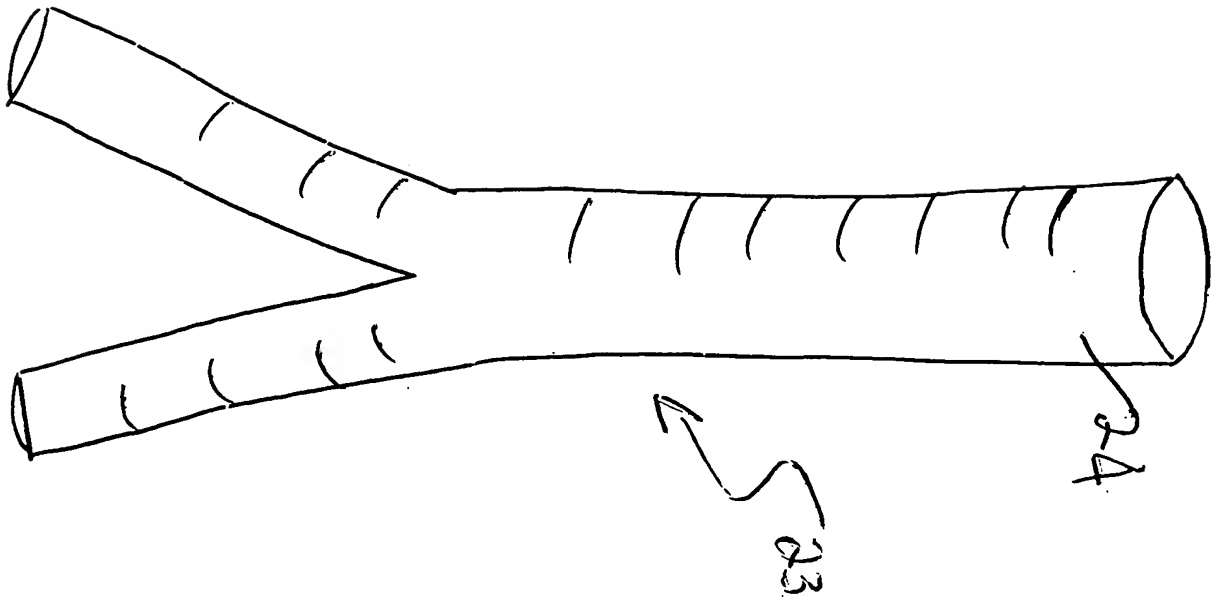


Figure 1

Fig 2



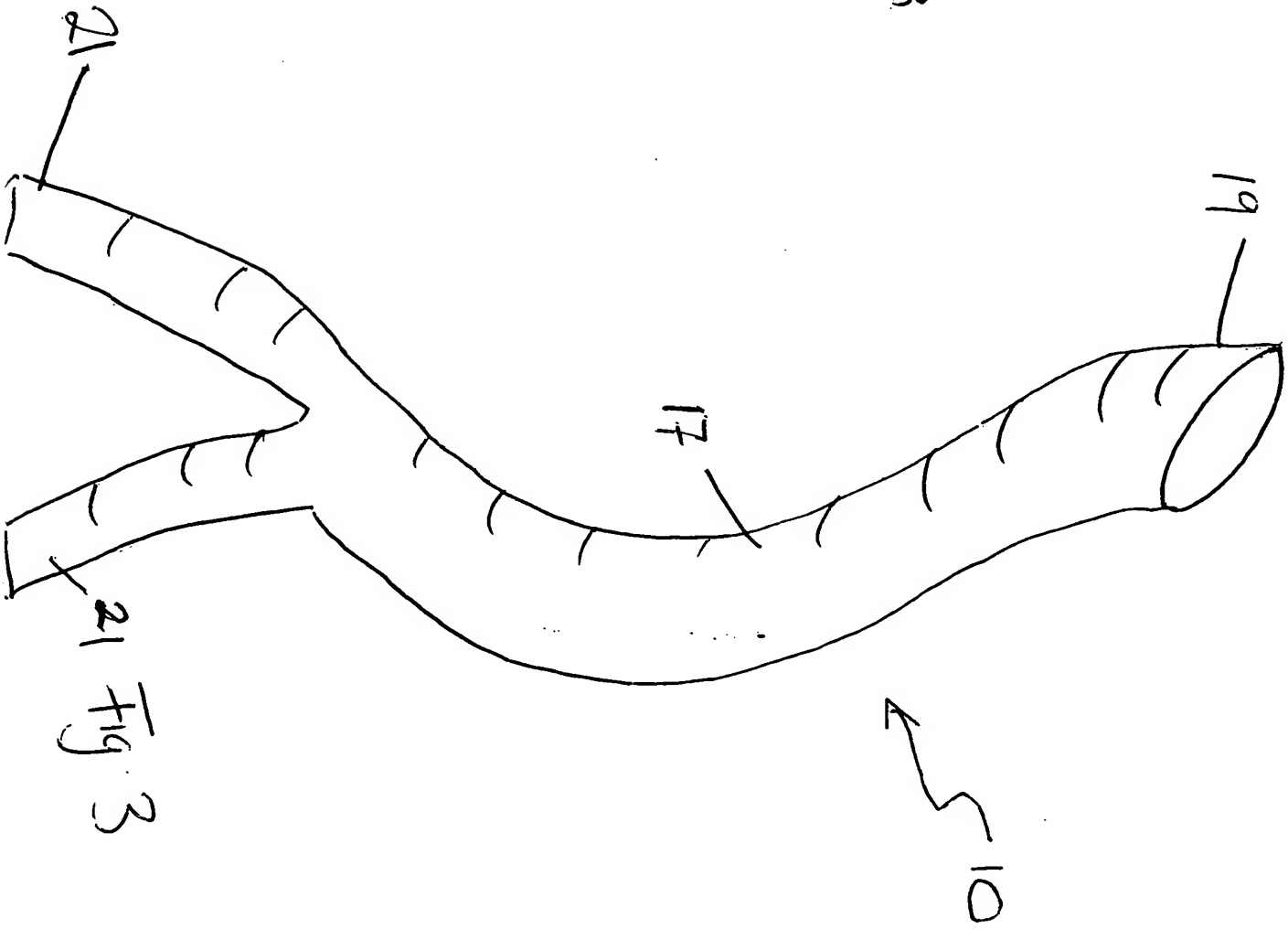


Fig 3

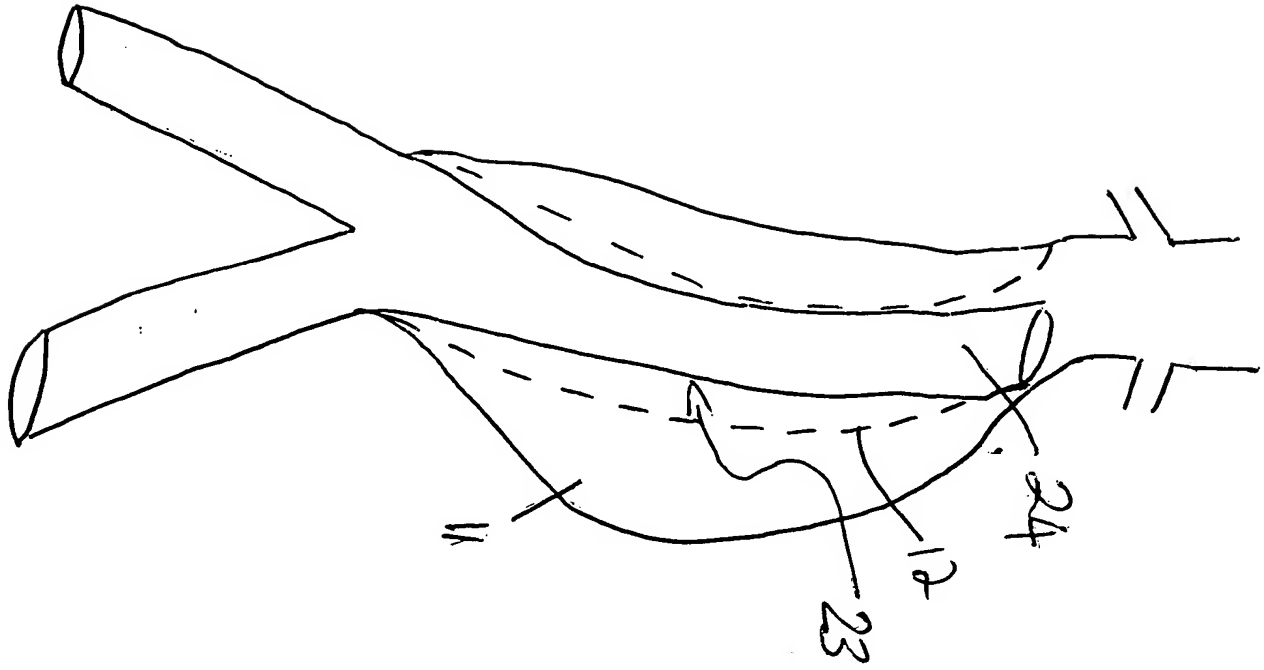


Fig 4

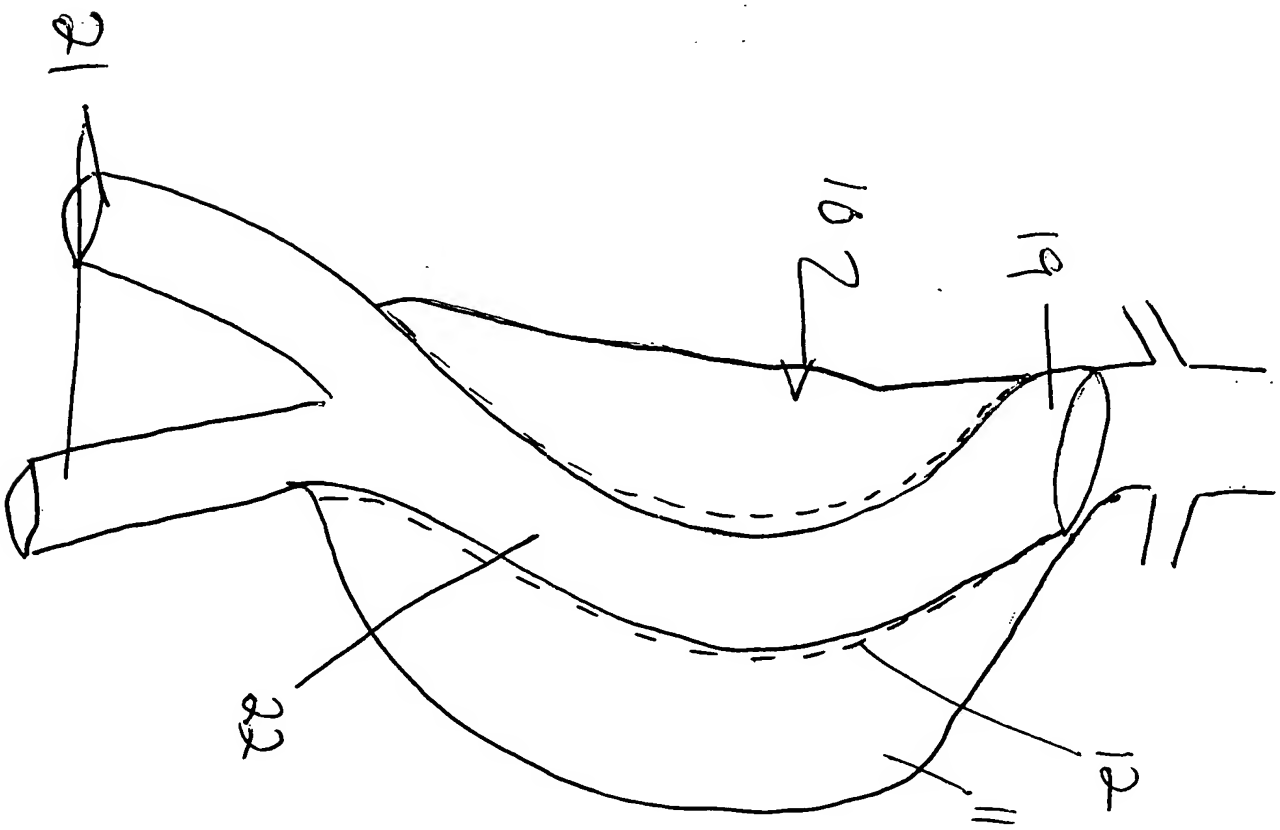


Fig 5

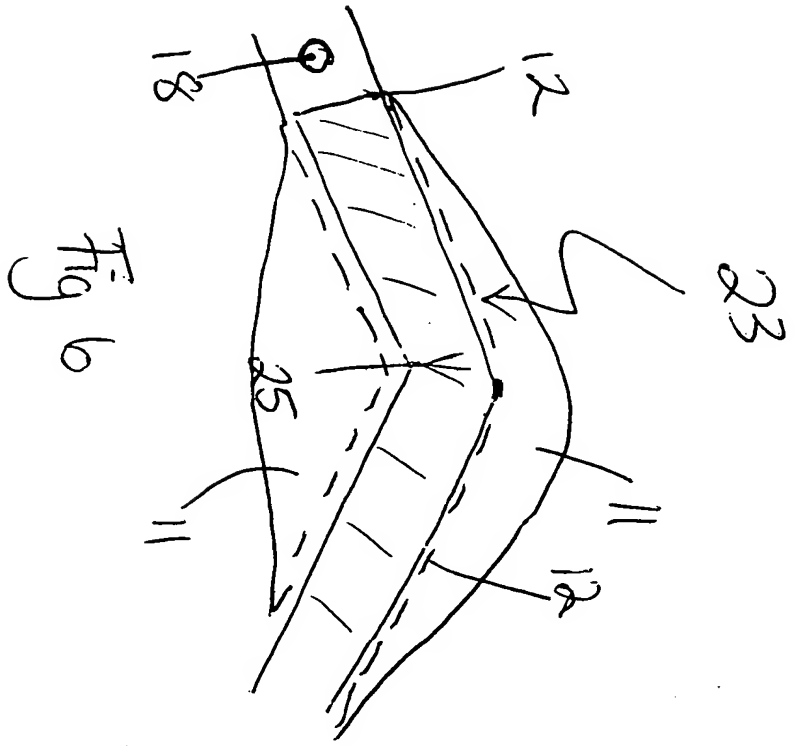


Fig 6

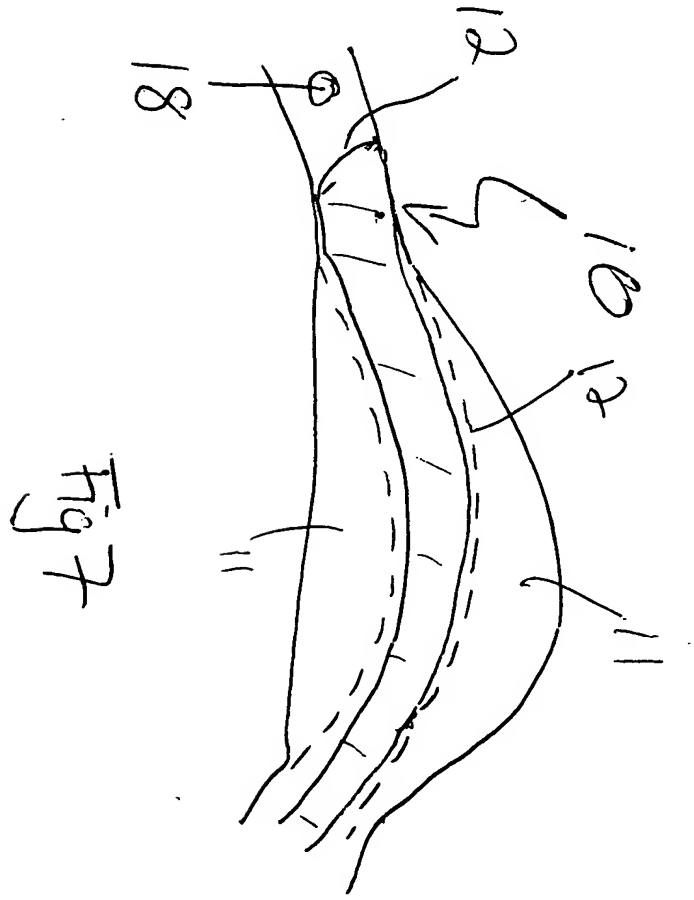


Fig 7

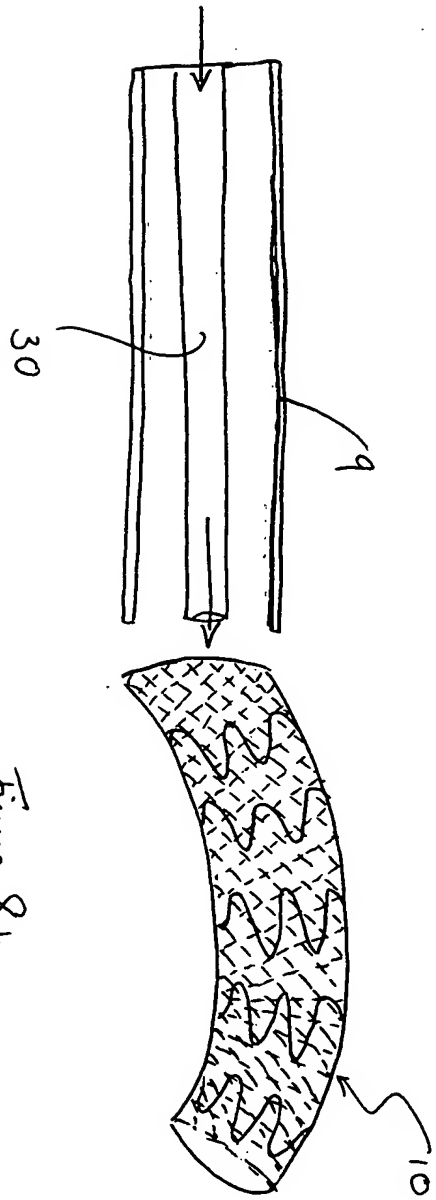


Figure 8b

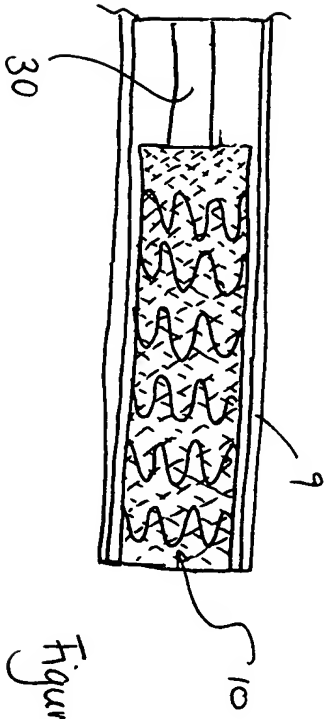


Figure 8a